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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/797,164 | 03/09/2004 | Dale R. Pfost | 56548-015 | 4027 |

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| EXAMINER | |
|---|---|
| MYERS, CARLA J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/797,164 | PFOST, DALE R. | |
| | Examiner | Art Unit | |
| | Carla Myers | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *28-53,55 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *28-53, 55 and 56* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Election/Restrictions***

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented claims 34-40, 53, 55 and 56 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The claims are improperly joined as the claimed methods require the analysis of distinct target molecules – i.e., nucleic acids and proteins. A reference against the analysis of one target molecule would not necessarily constitute a reference against the other target molecule. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 28-32 and 41-42, drawn to methods of increasing treatment efficacy by selecting compounds that exhibit the highest overall mean response to all dosing options, classified in class 424, subclass 9.2.

II. Claim 33, 43-52, drawn to methods which identify compounds that are minimally toxic and effective for at least 1% of the population, classified in class 424, subclass 9.2.

III. Claims 34-40, 53, 55 and 56, drawn to methods of genotypically-facilitated methods of treatment which comprise determining an association between a SNP in a nucleic acid and efficacy of a therapeutic compound, classified in Class 435, subclass 6.

IV. Claims 34-40, 53, 55 and 56, drawn to methods of genotypically-facilitated methods of treatment which comprise determining an association between a SNP in a protein and efficacy of a therapeutic compound, classified in Class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are drawn to patentably distinct inventions. Each invention is drawn to a distinct method which involves the use of different reagents, involves performing different method steps and/or has different outcomes or objectives. In particular, invention I requires the steps of analyzing compounds for their efficacy and selecting a combination of compounds that exhibit the highest overall mean response of all dosing options. The method of invention II requires determining the efficacy of a plurality of compounds, determining the toxicity of a plurality of compounds and selecting a combination of compounds that are minimally toxic and which are effective for at least 1% of the population. The method of invention III requires reagents such as nucleic acid primers and probes and involves the steps of analyzing a target nucleic acids for the presence of a SNP using methods such as nucleic acid sequence, amplification or hybridization, identifying compounds whose efficacy is associated with the presence of the SNP in a nucleic acid, and administering a combination of compounds to a population. The method of invention III requires reagents such as proteins, antibodies and protein sequencing reagents and involves the steps of analyzing a target protein

for the presence of a SNP using methods such as protein sequence or antibody binding assays, identifying compounds whose efficacy is associated with the presence of the SNP in a protein, and administering a combination of compounds to a population.

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-IV require different searches that are not co-extensive. For instance, a keyword / literature search for the methods of invention I would not be co-extensive with a keyword / literature search for the methods of invention II-IV. Further, a finding that the method of invention I is anticipated or obvious over the prior art would not necessarily extend to a finding that the methods of invention II, III or IV were also anticipated or obvious over the prior art. Similarly, a finding that the method of invention I is novel and unobvious over the prior art would not necessarily extend to a finding that the methods of invention II, III, and IV are also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00

PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
July 3, 2006

CARLA J. MYERS
PRIMARY EXAMINER